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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,385	08/24/2001	Scott Levine		3458

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Scott Levine MD  
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Orlando, FL 32819

EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/01/2004

9

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

# Office Action Summary

Application No.

09/939,385

Applicant(s)

LEVINE, SCOTT

Examiner

Traviss C McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 24-64 is/are pending in the application.
- 4a) Of the above claim(s) 42-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-41 and 64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Groups I and II in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

An action on the merits of claims 24-41 and 64 is contained herein below.

Claims 42-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29, 34, 39, and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.*

In the amendment filed by applicants on July 25, 2003, applicants have amended claims 29 and 39 to include dog bones as a possible form of the composition. Applicants do not have support for the claims as amended in the specification as originally filed. The original disclosure does not provide any guidance for indicating that the composition can be in the form of a dog bone. The changing of the scope of a claim, either by broadening or narrowing, can be construed as new matter as either is capable of changing the scope of what is claimed, and the narrower or broader group must be supported in its entirety by the specification as originally filed. As set forth supra, the original disclosure does not have support for dog bones. Applicant is required to cancel the portion of the claims which states that the composition can be a dog bone.

In the amendment filed by applicants on July 25, 2003, applicants have amended claims 34 and 41 wherein the composition optionally includes "plant derived compounds" or "synthetic orally absorbable nontoxic compounds", and claim 41 additionally includes "orally consumed substances that induce weight loss". Applicants do not have support for the claims as amended in the specification as originally filed. The original disclosure does not provide any guidance for indicating that the composition can include any item which falls within the broad groups of "plant derived compounds", "synthetic orally absorbable nontoxic compounds", or "orally consumed substances that induce weight loss". The changing of the scope of a claim, either by broadening or narrowing, can be construed as new matter as either is capable of changing the scope of what is claimed, and the narrower or broader group must be supported in its entirety by the specification as originally filed. As set forth supra, the original disclosure does not have

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support for the broad groups of “plant derived compounds”, “synthetic orally absorbable nontoxic compounds”, or “orally consumed substances that induce weight loss”. Applicant is required to cancel the portion of the claims which contains these limitations.

If applicants believe they do indeed have support in the specification as originally filed, they are encouraged to point to the page and line number of the disclosure as originally filed which supports the claims as they currently stand.

It is noted that a rejection of the claims is reviewable by the Board of Patent Appeals and Interferences.

Claims 26-29, 34, 36-41, and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is drawn to a composition comprising guar, oat, psyllium, and a flavoring agent, and to further include at least one ingredient admixed to create an edible food product selected from liquids, semisolids, and solids, which is seen to be missing a critical element. The claim fails to particularly point out the identity of the additional ingredient to be used in the composition instantly claimed. The current claim language is drawn to a composition which is not described structurally/formulaically/nomenclatorially; but rather by it's intended use, function or effect requisite to an activity produced by the composition. The claim is missing the

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critical element, which is the particular or distinct identity of the additional ingredient to be used in the composition. Compositional ingredients should be stated to indicate what they are, not what they are intended to do or what action they are intended to perform (i.e., to form a liquid).

Claim 27 is indefinite wherein the claim limits claim 24 by including at least one edible fiber selected from soluble, partially soluble, and insoluble fibers into the composition. However, it is unclear as to what the additional fiber is to be soluble, partially soluble, or insoluble in. Moreover, it is unclear as to why the phrase "selected from the group consisting of soluble, partially soluble, and insoluble fibers" is included in the claim, as this appears to allow any additional edible fiber into the composition and seems to be redundant as the claim could stand alone without this recitation.

Claim 28 is indefinite wherein the claim further limits claim 24 by including "at least one edible liquid selected from the group of liquids consisting of zero calorie and calorie containing liquids", as this allows any liquid to be included therein. It is unclear why applicants are intending to limit the additional agents with Markush groups as currently set forth (i.e., with groups which include everything).

Claim 29 intends to limit the composition of claim 24 by including at least one ingredient admixed to create an edible food product selected from semisolids and solids, which is seen to be missing a critical element. The claim fails to particularly point out the identity of the additional ingredient to be used in the composition instantly claimed. The current claim language is drawn to a composition which is not described structurally/formulaically/nomenclatorially; but rather by its intended use, function or effect requisite to an activity produced by the composition. The claim is missing the critical element, which is the particular or distinct identity of the additional

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ingredient to be used in the composition. Compositional ingredients should be stated to indicate what they are, not what they are intended to do or what action they are intended to perform (i.e., to form a pudding).

Claim 30 is indefinite wherein the claim intends to limit the flavoring agent of claim 24 to “sweeteners or substances that provide flavor”. It is unclear how “substances that provide flavor” can further limit a “flavoring agent” as these are the same thing.

Claim 34 is indefinite wherein the claim intends to limit claim 24 by including “plant derived compounds or synthetic orally absorbable nontoxic compounds”. This recitation is indefinite as it is unclear as to exactly what a “plant derived compound” or a “synthetic orally absorbable nontoxic compound” is intended to be. Applicant is defining the additional agents by their source or their action, and as set forth supra, applicants should define the additional agents structurally/formulaically/nomenclatorially, not by their source or activity.

Claim 36 is indefinite wherein the claim intends to add an additional agent to claim 24, wherein a flavoring agent is optionally added. However, claim 24 already includes at least one flavoring agent, thus, if the additional agent of claim 36 which is added from the Markush group is “at least one flavoring agent”, it is unclear how this would limit claim 24, as claim 24 already has at least one flavoring agent.

Claim 37 is indefinite wherein applicant claims methods of “reducing the risk of developing and aiding in the treatment of...”. It is unclear if applicants intend this to represent prevention (as in reducing the risk of developing). Applicants are encouraged to amend the claim to read as “methods of treating...”.

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Claim 37 is indefinite as the phrase “abnormal serum cholesterol” is unclear. At what level is the serum cholesterol considered to be abnormal? Moreover, applicants should place the word “and” between “syndrome” and “abnormal” wherein the claim would read “treating overweight, obesity, insulin resistance, glucose intolerance, diabetes, cardiovascular disease, metabolic syndrome, **and** abnormal serum cholesterol, lipids, lipoproteins, and triglycerides”.

Claims 38 and 39 are indefinite for the inclusion of “liquids containing zero calorie and calorie containing liquids” for the same reasons as set forth supra for claim 28.

Claim 40 is indefinite for the inclusion of “soluble, partially soluble, and insoluble fibers” for the same reasons as set forth supra for claim 27.

Claim 41 is indefinite for the inclusion of “plant derived compounds, synthetically orally absorbable nontoxic compounds,... and orally consumed substances that induce weight loss” for the same reasons as set forth supra for claim 34.

Claim 64 is indefinite wherein the claim is drawn to a supplement comprising items a-e. However, it is unclear if applicant intends the 7 grams of fiber in (c) to be an additional fiber requirement beyond the guar, oat, and psyllium, or if applicant intends this to define the amount of oat, guar, and psyllium. Moreover, does applicant intend the liquid of (e) to be in addition to the liquid of (e)? Clarity is respectfully requested.

Claim 64 is additionally indefinite wherein the term “immediately” is a relative term which renders the claim indefinite. The term “immediately” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Immediately could mean within 1 second, within 10 seconds, within a minute, or within an hour.



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Applicants are encouraged to define the time frame which is envisioned in a numerical manner which would clearly set forth the metes and bounds of the claim.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).*

***Claim Rejections - 35 USC § 102***

Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection.

Claims 24-27, 29-31, and 34-36 rejected under 35 U.S.C. 102(b) as being anticipated by Ringe et al. (US Patent 5,026,689), newly cited.

Claim 24 is drawn to a composition comprising at least 7 grams of fiber per serving and comprising a mixture of guar, oat, psyllium, and a flavoring agent. Claim 25 provides that the mixture comprises 1-15g of guar, 1-15g of oat, and 0.5-10g of psyllium. Claim 26 provides that there is an additional agent incorporated to create a liquid, semisolid, or solid product. Claim 27 provides that there is an additional fiber in the composition. Claim 29 provides that there is an additional agent incorporated to create a solid or semisolid of puddings, snack bars, or wafers. Claim 30 provides there is a sweetener. Claim 31 provides there is an additional agent, which is selected from coloring agents, preservatives, thickening agents, thinning agents, or emulsifiers. Claim 34 provides vitamins are optionally added, claim 35 provides that carbohydrates are optionally added, and claim 36 provides that a sweetener is optionally added.

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Ringe et al. disclose a composition comprising oat, psyllium, and guar, as well as a malt syrup (flavorant) wherein the fiber content is disclosed as being 7.2 g/oz (example 3) and 7.7 g/oz (example 4). Moreover, Ringe disclose that a dosage of 0.8-1.5 g/kg can be eaten 1-3 times daily (see column 3, lines 1-7). It is noted that an 80 kg person (about 150 lbs) would be required to ingest about 3 oz of product based on a 1 g/kg dosage ( $1 \text{ g/kg} = 80 \text{ g}/80 \text{ kg}$ ; 80g is about 3 oz). Moreover, the percentages by weight of the compositions of examples 3 and 4 are seen to be correlative to the weight in grams as set forth in claim 25 of the instant application. The product of Ringe et al. is disclosed as being a cereal (solid). Ringe et al. additionally disclose adding wheat bran to their composition (an insoluble fiber). Ringe et al. disclose that their composition can be fabricated into a variety of common cereal forms including shreds, biscuits, flakes, or any form, shape or size (column 7, lines 65-69). Moreover, Ringe et al. disclose the addition of sugar (a sweetener/carbohydrate) and a vitamin blend to their composition (see examples).

The compositions as set forth in Ringe et al. are seen to anticipate the compositions as set forth in claims 24-27, 29-31, and 34-36 of the instant application.

Claims 37 and 40-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Ringe et al. (US Patent 5,026,689).

Claim 37 is drawn to a method of improving the health of a mammal comprising orally administering a composition as set forth supra wherein the health benefit is optionally treating abnormal serum cholesterol. Claim 40 provides that additional fibers are added to the composition and claim 41 provides that various vitamins, etc., are added to the composition.

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Ringe et al. disclose various oat, psyllium, and guar compositions (together with additional fibers and vitamins) as set forth supra. Ringe et al. additionally disclose that their composition is effective in lowering blood serum cholesterol (column 8, lines 39-40).

The compositions and methods of treatment as taught by Ringe et al. are seen to anticipate the compositions and methods of treatment as claimed in the instant application.

Applicants are encouraged to draft the claims to distinguish patentably over the art of record in this application, wherein applicants novelty appears to be in the fact that they are able to combine oat, guar, and psyllium in various percentages into a liquid supplement which has a total fiber content of at least 7 grams of fiber.

### ***Conclusion***

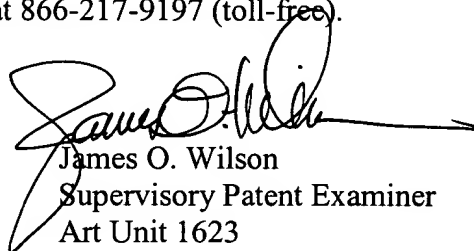
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III  
May 12, 2004



James O. Wilson  
Supervisory Patent Examiner  
Art Unit 1623